West Hertfordshire Hospitals NHS
NHS Trust

Agenda Item 108/11

Technical Specification for provision of Haematology Analysers for West Herts NHS Trust

1. Background

1.1 West Herts Hospitals NHS Trust requires proposals for delivery, installation, commissioning and maintenance of an automated system for haematology.

1.2 Any proposal **should** allow flexibility in changes of support for current configuration.

1.3 The objectives for procuring automated systems are:

- ✓ To augment staff time efficiencies.
- ✓ To improve turnaround times by supporting continuous 24/7 testing.
- ✓ The Suppliers proposal **must** fully satisfy these objectives.

1.4 For current workload stats see appendix 1.

1.5 Proposals are required for processing of the current workload as stated and costs for a 5 and 10% annual growth. These figures **should** be provided separately within the proposal. The document **must** address but not be limited to the whole life costs for:

- ✓ Delivery
- ✓ Installation
- ✓ Commissioning
- ✓ Consumables
- ✓ Reagents
- ✓ Quality Control
- ✓ Maintenance of the equipment
- ✓ Bi-directional interface to the laboratory computer system
- ✓ Training
- ✓ Disposal of equipment at the end of its life.
- ✓ Any modification of the laboratory estate to facilitate the equipment.

1.6 The Tender **must** warrant that the prices will, for the period of the Contract, be the best available in the UK. The Tender **must** detail how they will conform to the requirement.

1.7 It is a requirement the current laboratory output **must** be maintained during installation and acceptance testing of the automation.

1.8 Proposals **must** be able to demonstrate (from current users) a high level of satisfaction regarding the automation, products, technical support and customer care.

1.9 The Supplier and their automated users **must** have a proven track record in the supply of Haematology analysers and **must** be able to show satisfaction by other reputable clinical laboratory users and NEQAS.

1.10 The Supplier **must** provide any MHRA or any other relevant evaluations that have been undertaken with respect to the equipment and/or reagents.

1.11 The Supplier **must** provide details of their support infrastructure detailing the number of engineers dedicated to the tendered analyser in the UK.

1.12 The requirements of this Tender Specification must be available at the time of installation.

2. General Analyser Specification

2.1 The equipment required as part of this tender are as follows:

- Full Blood Count [FBC] analysers.
- Erythrocyte Sedimentation Rate [ESR] analysers.
- Film making machines.
- Sample sorting and filing machine.
- Track system, where available.

The proposed configuration and positioning of this equipment is as follows:

Watford General Hospital

- 1 main FBC analyser with full functionality.
- 1 backup FBC analyser with a minimum capability of a 5-part leucocyte differential.
- 1 ESR analyser.
- 1 Film making machine.

Hemel Hempstead General Hospital

- 2 main FBC analysers with full functionality with track capability, where available.
- 1 ESR analyser.
- 1 Film making machine.
- Sample sorting and filing machine connected to the track capability, where available.

NB For further information please see appendix 1.

2.2 The supplier must provide details on how it will accommodate the proposed configuration and facilitate the specific requirements for each site.

2.3 Proposals **must** specify the equipment, hardware, software and the Un-interruptible Power Supply [UPS]. It is **desirable** that the UPS will shut down the analysers when the main power supply is cut.

2.4 All instruments **must** be capable of automatic recovery in the event of a power failure. The recovery **must** be complete and without loss of data, except any analysis being carried at the time of power failure.

2.5 All equipment proposed **must** be automated, and capable of random access at all times.

2.6 Details of guaranteed uptime (and its definition) **must** be provided. Details on how uptime is measured, how this will be attained, and remedies to the West Herts Hospitals NHS Trust if the uptime is not maintained are required to be submitted.

2.7 A fully automated backup system **must** be provided within 24 hours when the current equipment is deemed unrepairable. The Tender **must** provide details of how this will be achieved.

2.8 The analysers **must** be able to analyse EDTA samples.

2.9 The range of tests that **must** be available on the machine(s) are (but not limited to) the following:

2.9.1 Full Blood Count [FBC] including 5 part differential as a minimum:

Hb

RBC

HCT

MCV

MCH

MCHC

PLT

WBC

Neutrophils

Lymphocytes

Monocytes

Eosinophils

Basophils

2.9.2 Reticulocyte Counts [Retics].

2.9.3 Nucleated Red Blood Cells [NRBC].

2.9.4 Erythrocyte Sedimentation Rate [ESR].

2.10 The 5-part leucocyte differential **must** be stable and accurate between 0 minutes and 48 hours after the sample has been taken.

2.11 Each analyser **must** reliably report leucocyte counts of less than $0.2x10^9$/l and preferably give a 5-part differential on each. Analysers **must** be accurate to a platelet count of $5x10^9$/l and Haemoglobin of up to 25g/dl.

2.12 Each analyser **should** be able to report accurate and precise leucocyte counts of up to $400x10^9$/l.

2.13 Each analyser **must** generate visual flags to alert operators to the presence of abnormal leucocyte, red blood cell and platelet populations. The format of flagging (e.g. asterisk, back-lighting, etc) **should** be stated and how this information will be conveyed to our host computer.

2.14 Each analyser **must** be capable handling osmotically resistant red blood cells e.g. neonates and liver disease and produce a valid leucocyte count on such samples.

2.15 The supplier **must** state linearity values for leucocyte, red blood cell and platelet counts.

2.16 The supplier **must** state the highest acceptable background values for leucocyte, red blood cells, platelets and haemoglobin.

2.17 Supplier **must** state minimum performance characteristics for accuracy and precision.

2.18 The analysers **must** be capable of running <u>without</u> continual operator presence. The suppliers **must** state the maximum throughput of the analysers under optimal working conditions.

2.19 The proposed system **must** allow customer definable password protection levels and users (where applicable).

2.20 Start up, shut down, calibration, QC and local maintenance and general cleaning procedures **must** be stated and the length of time involved and required frequency of these procedures.

2.21 The Supplier **must** state size of the analysers including PC and any other peripheral equipment and the space thereof required. Requirements and consumption rates for power, water, drainage and air conditioning **must** be stated and installation costs included.

2.22 Details of any additional consumables, special waste containers **must** be provided and full costs provided.

2.23 Proposed system(s) **must** conform to current EC directives for in vitro diagnostics (IVD), electrical safety (CE) and CPA requirements or equivalent.

2.24 Fully detailed operator manuals **must** be provided. Such manuals **must** be renewed as and when the instrument software or hardware is updated and **must** be supplied in English. An onboard troubleshooting guide **should** be provided.

2.25 The West Herts Hospitals NHS Trust will expect all safety upgrades or enhancements to the equipment to be undertaken free of charge.

3. Data Processing and Storage

3.1 Proposed equipment **must** be compatible with the laboratory's LIMS, currently Cerner Classic and any future LIMS systems. The Tender **should** state how many installations of the proposed systems are interfaced with the LIMS, giving location and contact information for each.

3.2 Interfaces **must** be operable before "go live" and noted in a project plan or key stage document with the submission. The Tender **must** also advise of any remedies if the proposed project plan is delayed.

3.3 Data transfer **must** be automatic, on-line and bi-directional, but **must** also be able to cope with LIMS downtime. The Tender **must** provide details that this is possible within the proposed equipment.

3.4 The analysers **must** be able to run off line if the LIMS system is unavailable. Software **should** allow input of patient data to facilitate printing of temporary reports. Batch transmission of results **must** be available for when LIMS system is working again. The supplier **must** state how samples can be processed in the absence of the LIMS system being unavailable.

3.5 The requirement for a data manager, either supplied as original equipment or as an adjunct to the equipment **must** be stated. The precise specification and functionality of such a data manager **must** be clearly stated.

3.6 Where the equipment proposed has several linked analysers it **must** be possible for the other analysers to continue operating if one or more of the analysers are in operable for whatever reason.

3.7 There **must** be a fully recoverable back up system for the storage of analyser software as well as testing profiles and result data. The data manager **must** have the ability to store patient records to a minimum of 20,000 or 3 months whichever is greater. The format in which the data is stored **must** be stated.

3.8 The cost of interface development, installation, licence and maintenance **must** be included in the system cost and set out in the pricing schedule. The pricing **must** include both sides of the interface.

3.9 There **must** be a reagent inventory system. This **should** utilise bar coded entry of lot number and expiry date. Proposed reagent bottles **should** carry this information. Data **must** be retrievable with method of archiving stated.

3.10 Reflex testing **must** be user definable.

3.11 There **must** be systems available to automatically validate results for transmission to the host system. Error flags **must** be clearly visible.

4. Sampling requirements

4.1 Cap piercing facility **must** be available, proposals **must** state if cap piercing is available by the proposed equipment.

4.2 The analyser **must** be capable of accepting a variety of primary sample tubes in the same carrier with the ability to function with all current commercially available evacuated tubes. Small volume paediatric samples **must** be accommodated. The minimum volume requirements for all sample tube sizes **must** be stated. The tender **must** state the dead volume of each specimen being sampled.

4.3 Sample tube sizes and types that are not compatible with the proposed equipment **must** be clearly stated.

4.4 The system **must** be capable of reading and sampling from bar coded primary tubes. The system **must** be compatible with Codabar and ISBT128 bar codes. State all other barcode configurations that are readable by the proposed equipment.

4.5 Although the requirement is for a random access analyser it **must** be capable of working in batch mode if required. The supplier **must** state the maximum number of samples that can be loaded at any one time. Urgent samples **must** be able to be added – the supplier **must** state how these are prioritised.

4.6 The analyser **must** be capable of analysing high-risk samples with minimum risk to the operator. The supplier **must** confirm that decontamination procedures are available and state duration of down time while in process.

4.7 The equipment **should** be able to display the time required until the result(s) of test(s) is/are accessible, for example ESR analysis.

4.8 The sampling system **should** have level sensing, clot detection, bubble sensing and short sample alerts both audible and visual. Warnings **must** be given when there is an error. The supplier **should** state the method of clot removal from the system, where apparent.

4.9 The sampling system **should** not be influenced by the presence of bilirubin, lipaemia, high protein content etc. Methods of minimising such interference **must** be stated.

4.10 There **must** be no significant carry-over of samples.

5. Reagent Requirements

5.1 The equipment **must** have level detection and be able to calculate if there are any shortfalls in either reagents or consumables to complete a batch of work and alert the operator immediately. The alert **must** be both audible and visual. It **should** also have a countdown system for each reagent and consumable.

5.2 Suppliers **must** state how sample and reagent deterioration is minimised while on board. The maximum viability of reagents on board **must** be indicated i.e. installation, registration and removal.

5.3 All reagents **must** be bar coded. The equipment **must** be capable of reading bar coded information from reagent packs. As a minimum, batch number, expiry date and date of placing on the equipment **must** be recorded and recoverable. The format in which the data is stored **must** be stated.

5.4 A complete range of required reagents **must** be available and **must** be CE marked.

5.5 The instrument **must** not allow time expired reagents to be used.

5.6 The supplier **must** be able to supply reagents/protocols for the following assays:

5.6.1 NRBC.

5.6.2 Retics.

5.7 State storage requirements for one month and six weekly supplies of reagents and consumables including space required at room temperature or refrigerated. State temperature limits for both.

5.8 State guaranteed minimum shelf life of products provided.

5.9 Provide details of standard and emergency orders for reagents and the lead-time and cost.

5.10 Details of any third party consumables that are compatible with the proposed systems **must** be provided.

5.11 Use of said third party consumables **must** be supported and protocols for their use **must** be available.

6. Calibration and Quality Control (QC)

6.1 There **must** be fully auditable systems in place for reagent use, sample testing systems, Quality Control [QC] and Quality Assurance [QA] including run times, back up times and user logons and editing.

6.2 There **must** be access to test and QC/QA results and all other data without interruption to the analyser runtime.

6.3 The system **must** have monitoring of all aspects of instrument performance.

6.4 Submissions **must** include details of the QC material proposed and any associated cost.

6.5 It **must** be possible to use other manufacturers materials.

6.6 Proposals **must** specify the recommended frequency of QC.

6.7 All QC material **must** be bar-coded.

6.8 QC results **must** be clearly indicated with appropriate status flags against defined results i.e. out of limit results.

6.9 The system **must** not normally allow testing to proceed where the QC data is outside the prescribed limits or where the QC has not been performed in accordance with the system configuration. There **must** be a security protected override for this. Any results generated with the override activated **must** be flagged to show this.

6.10 Details of QC handling programs on the equipment **must** be given and **must** show SD, CV and mean results. The onboard storage capacity of QC data **must** be given and **must** be extractable in an appropriate format.

6.11 The QC batch numbers, targets, results and an on-board comment facility **must** be available for storage suitable for accreditation purposes.

6.12 Details of onboard validation, approval and checking of patient results **must** be given. Automatic validation of results within user-defined limits **must** be available.

6.13 The supplier **must** state the methodology used for reading, how so performed and the evaluation data of the reading system.

7. Maintenance

7.1 Routine maintenance **must** be auditable, including operator identification.

7.2 The daily, weekly and monthly maintenance procedures **must** be described.

7.3 There **must** be an onboard maintenance and fault/error log with archiving and recoverable data. The format in which the data is stored **must** be stated.

7.4 The quantity, frequency and duration of preventative maintenance visits per annum **must** be stated and a schedule of works **must** be provided.

7.5 Maintenance contracts available **must** be described along with the guaranteed response times for callouts. State the support available at night, at weekends and public holidays. The times during which technical support is available **must** be stated.

7.6 Fully detailed operator manual **must** be provided in English printed and on-line.

7.7 State the level of "self-help" available from the manuals.

7.8 State whether on-line manuals are available.

7.9 A guarantee **must** be provided that the proposed equipment will be supported and spares available for a minimum of seven years.

8. Training

8.1 The supplier **must** provide details of a comprehensive training program for laboratory staff stating the number of places offered and how the training will be achieved. The suppliers **must** also state what support is provided to cascade training to junior staff. The training package **must** be available for the lifetime of the contract.

8.2 Proposals **must** include details of the training courses included with the supply of automation, including the number of places available and the duration and location of the courses. Provide an example of a training prospectus for the system.

8.3 State whether additional courses are available at a later date and whether any on-site training is included and what it involves.

8.4 Details of any user groups in the UK and the frequency of meetings including regular updates **must** be provided; proposal of support **should** be included.

9. Environmental and Health & Safety

9.1 The proposed equipment **must** comply with relevant regulations for electrical, mechanical and biological safety and copies of the appropriate certification provided.

9.2 All reagents proposed **must** comply with relevant regulations regarding shipping, labelling and information on hazardous substances. COSHH data **must** be confirmed as available and **must** be supplied in advance of installation.

9.3 Provide details of waste disposal requirements including any special precautions for handling "High Risk" samples or waste.

9.4 A decontamination procedure for the equipment **must** be provided with recommendations (including recommended cleaning products) of when it **should** be used.

9.5 Suppliers **must** state whether there are any reagents or consumables that require Manual Handling Precautions. Dimensions and weight of all components **must** be provided.

9.6 Details of ambient temperature and humidity ranges **must** be stated together with maximum heat output.

9.7 Details of power supply requirements and consumption **must** be provided.

9.8 Suppliers **must** state any requirements for the equipment and **must** outline the costs involved. These costs **must** be borne by the supplier. This will include: whether the system requires a water feed, in which case the volume, quality and pressure of the water will be required; and also if the system requires any special ventilation, i.e. waste gases of chemicals which would need venting to the outside. All requirements **must** be stated.

9.9 The analyser **should** have an emergency STOP feature and a protective shield **must** be in place whilst the analyser is running.

10 Additional Information

10.1 A policy **must** be provided on the recall and replacement of equipment, reagents and consumables.

10.2 A policy **must** be provided on the investigation of any untoward/anomalous event in the use of any equipment, reagents and consumables supplied by the tender.

10.3 The supplier **must** supply details of any hardware and software upgrades that **must** be free of charge. The supplier **must** guarantee that any software upgrades are virus free before installation. The supplier **must** provide a policy on how this is achieved. This **must** include an audit trail of the upgrade including changes in the functionality of the operating system. Training **must** be provided where necessary.

10.4 The supplier **must** state if software upgrades are available via the Internet and if so are N3 compliant.

10.5 It is expected that the reagents and consumables delivery dates will be provided. The supplier **must** state how this will be achieved and provide a schedule. The supplier **must** keep an inventory of reagents dispatched.

10.6 The supplier **must** support ad hoc deliveries of extra reagents and both sites due to changing workload patterns may require consumables. The cost of these **must** be stated.

10.7 The supplier **must** provide details of arrangements that will be put in place if reagents and consumables are subjected to manufacturing or supply problems in a timely manner.

10.8 The equipment **must** be available for delivery by December 2009.

10.9 The supplier **must** state the expected time for delivery, installation and full commission; this **must** include a fully functional interface after any order is placed. The supplier **must** state what is required at the time of installation.

10.10 The supplier **must** undertake any future relocation and reconfiguration of analytic arrangements.

10.11 The Tender **must** state the capital cost. The costing **must** include all items required for full and complete installation and operation of the system in compliance with the preceding specification.

10.12 The Tender **must** state clearly those items of the specification that are not available or cannot be supported.

10.13 The Tender **must** state the warranty period and the extent to which such a warranty will apply.

10.14 The Tender **must** state the full annual cost of the reagents and consumables based on the figures supplied in appendix 1. This includes an estimated wastage cost in reagents, cells and consumables over the same period.

10.15 The Tender **must** state the full annual cost of the Maintenance and Service agreement for the duration of the contract.

10.16 The Tender **must** state the full annual cost of a Managed Service Contract if available.

10.17 All equipment (including any instrument associated PC workstations) **must** be protected from spikes and breaks in power supply by the provision of dedicated UPS systems, which **must** have sufficient power to allow any assays in progress to be completed and allow controlled shutdown of the instrument.

10.18 The Tender is invited to include any other information, which they deem relevant in support of their proposal.

10.19 The Tender is invited to include any significant advances that are under development and provide details of availability. If advances are identified please state how these would be provided and any related costs.

Appendix 1

The predictive workload for 2009/2010 in each laboratory is as follows:

Test	WGH	HHGH	Totals
FBC	155,400	233,100	388,500
Retics	7,000	2,000	9,000
NRBC	2,500	500	3,000
ESR	25,000	43,000	68,000

The figures are an approximation based on the service reconfiguration that has taken place in March 2009, whereby all non-urgent work including GP work was transferred to the Hemel Hampstead site. This site currently operates Monday to Friday from 08:00 to 20:00 hours. The Watford site provides a full 24/7 service for Acute, Accident & Emergency and Inpatient work including supporting Haematology Ward and Clinical work.